RVD2009-06

Re-evaluation Decision

Naphthalene Acetates

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

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Overview

Re-evaluation Decision

After a re-evaluation of the plant growth regulators naphthalene acetates, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing naphthalene acetates for sale and use in Canada.

An evaluation of available scientific information found that products containing naphthalene acetates do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of naphthalene acetates uses, new risk-reduction measures must be included on the labels of all products. No additional data are required at this time.

The regulatory approach for the re-evaluation of naphthalene acetates was first presented in Proposed Re-evaluation Decision PRVD2008-28, *Naphthalene Acetates*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of the PMRA's regulatory process for the re-evaluation of naphthalene acetates as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-28. To comply with this decision, registrants of products containing naphthalene acetates will be informed of the specific requirements affecting their product registrations.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Naphthalene acetates, one of the active ingredients in the current re-evaluation cycle has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of naphthalene acetates. In this decision, the PMRA took into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy [TSMP]).

The United States Environmental Protection Agency re-evaluated naphthalene acetates and published its conclusions in a 2007 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2008-28, *Naphthalene Acetates*.

What Is Naphthalene Acetates?

Naphthalene acetates are plant growth regulators due to their structural similarity to the natural plant growth hormone auxin, indole acetic acid. Auxin promotes growth in excised plant organs, induces adventitious roots, inhibits axillary bud growth and regulates gravitropism. Naphthalene acetates are used to delay flower induction and prevent preharvest fruit drop in orchard and ornamental trees.

Health Considerations

Can Approved Uses of Naphthalene Acetates Affect Human Health?

Naphthalene acetates are unlikely to affect your health when used according to the revised label directions.

People could be exposed to naphthalene acetates by consuming food and water, by working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The United States Environmental Protection Agency concluded that naphthalene acetates were unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes, through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Naphthalene acetates are currently registered in Canada for use on apples and pears and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for naphthalene acetates in Canada. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Naphthalene Acetates Are Introduced Into the Environment?

Naphthalene acetates are unlikely to affect non-target organisms when used according to the revised label directions.

Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The United States Environmental Protection Agency concluded that the reregistration of naphthalene acetates was acceptable. These conclusions apply to the Canadian situation. Furthermore, the PMRA will require terrestrial buffer zones for naphthalene acetates to protect terrestrial plants from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of naphthalene acetates, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- Protective equipment to protect mixer/loader/applicators.

Environment

- Buffer zones to protect non-target, sensitive terrestrial habitats.

all required label amendments.

Appendix I lists

Other Information

Any person may file a notice of objection[1] regarding this decision on naphthalene acetates within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd, or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[1] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Label Amendments for Products Containing Naphthalene Acetates

The label amendments presented below do not include all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following statements must be included in a section entitled **PRECAUTIONS**.

> Wear long pants, a long-sleeved shirt and shoes plus socks during mixing, loading, applying, cleaning and repair.

II) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS**.

> TOXIC to non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

III) The following statements must be included in a section entitled **DIRECTIONS FOR USE**.

> Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site, as measured outside of the treatment area on the upwind side.
>
> **DO NOT** apply by air.
>
> **Buffer zones:**
>
> Use of the following spray methods or equipment DO NOT require a buffer zone: hand-held or backpack sprayer and spot treatment.
>
> The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands.

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of Terrestrial Habitat:
Airblast	Apples, pears	4
Airblast	Ornamental crabapples	2